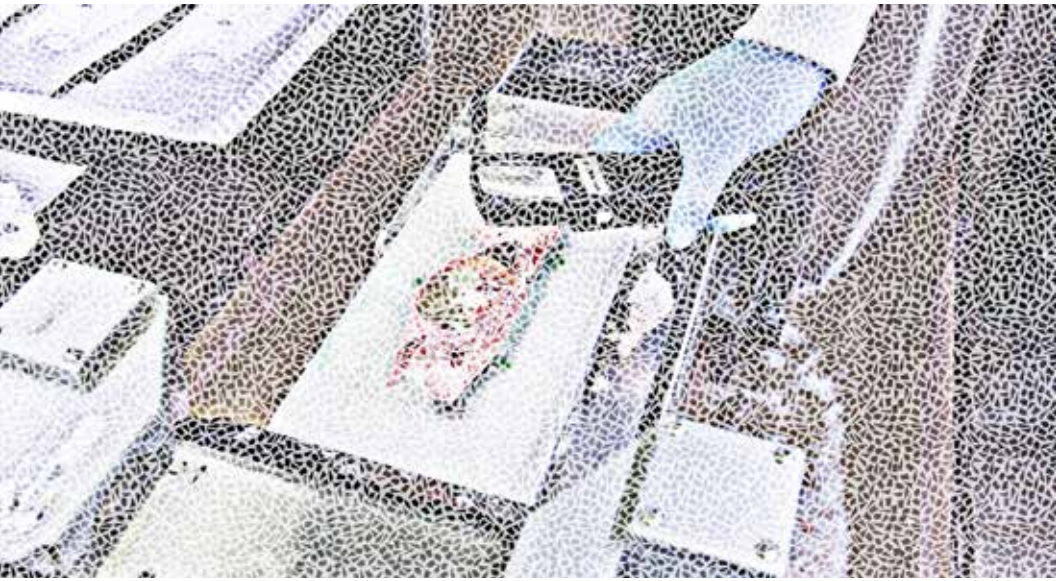
A FLEXIBLE APPROACH TO **RADIOLABELED ADME STUDIES**

HAVING ALL OF YOUR RADIOLABELED ADME STUDIES PERFORMED AT QPS SAVES YOU TIME AND RESOURCES. A well-conceived and executed preclinical and clinical radiolabeled ADME program will provide you with a detailed assessment of the total fate of your drug candidate to support regulatory submissions.



QPS
CUSTOM-BUILT RESEARCH™

RADIOLABELED ADME STUDIES AT QPS

Preclinical Radiolabeled ADME Studies:

- Mass Balance/Routes of Excretion
- Quantitative Whole-Body Autoradiography (QWBA)
- Microautoradiography (MARG)
- Plasma Protein Binding; RBC/Plasma Distribution
- *In Vitro* Species Comparison of Metabolism
- Metabolic Reaction Phenotyping
- Metabolite Profiling, Identification, & Radio-quantification

Radiolabeled hAME Studies:

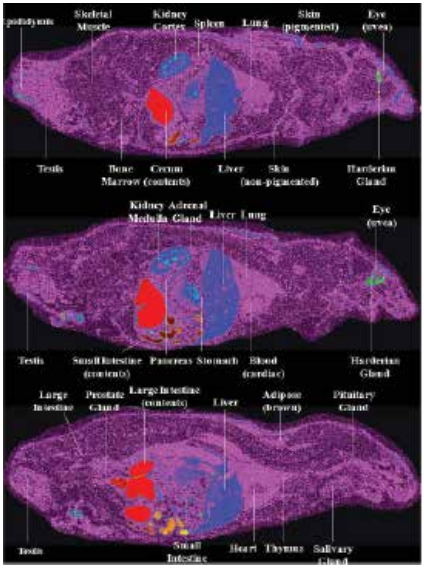
- Consultation and Preparation of Clinical Study Protocol
- Preparation of Human Radiation Dosimetry
- Ethics Committee & Competent Authority Submission; fast review and approval in 14 days after submission
- Preparation and Release of Radiolabeled IMP According to GMP Annex 13 by a Licensed Radio- pharmacy; this also includes measurement of radiochemical purity
- Drug Administration of Radiolabeled IMP by a Designated and Radio-licensed Research Physician; flawless execution of study according to protocol
- Collection, Processing, and Analysis of Radioactive Human Blood, Plasma, and Excreta (urine, feces, and expired air)
- Metabolite Profiling, Identification, & Radio-quantification
- Preparation & Submission of an Integrated Clinical Study Report (CSR)

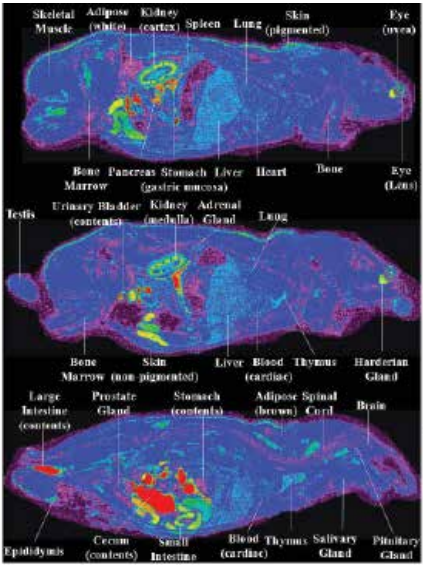
QPS IS A TRUE TURNKEY ADME STUDY PROVIDER THAT EFFECTIVELY EXECUTES YOUR RADIOLABELED STUDIES

By placing your studies with QPS, you will benefit from peer-to-peer communication with our expert ADME scientists who have extensive industry and CRO experience enabling optimal planning and execution of your studies.

A senior technical expert will be assigned to facilitate the rapid development of your drug candidate by shepherding the compound through the various studies within QPS: preclinical excretion/mass balance, QWBA, MARG (if necessary), profiling/identification/radio-quantification of metabolites, dosimetry calculation, and human mass balance studies.

Any compound specific and/or sample handling procedures will be seamlessly transferred between QPS preclinical and clinical teams to minimize delays at the different stages of drug development which ensures rapid generation and rigorous analysis of preclinical and clinical ADME data resulting in high quality regulatory-filing ready study reports.



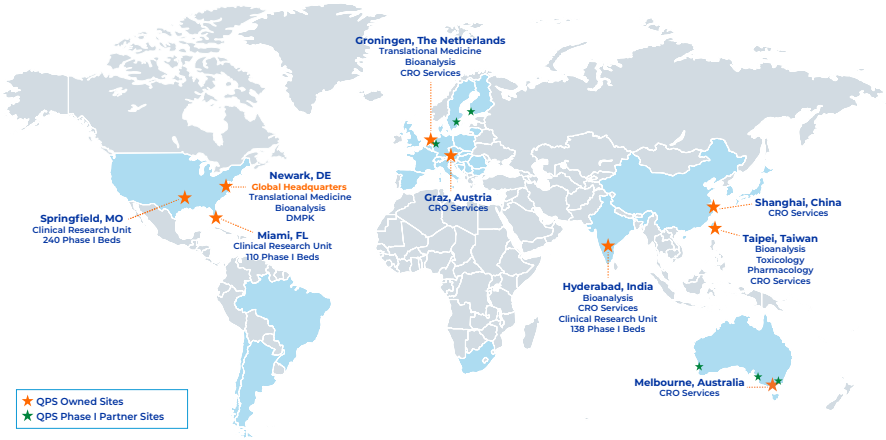


Evaluation of Metabolism and Disposition of GDC-0152 in Rats Using 14C Labeling Strategy at Two Different Positions: A Novel Formation of Hippuric Acid from 4-Phenyl-5-Amino-1,2,3-Thiadiazole. Qin Yue, Teresa Mulder, Patrick J. Rudewicz, Eric Solon, Nageshwar Budha, Joseph A Ware, Joseph Lyssikatos, Cornelis E.C.A. Hop, Harvey Wong, and S. Cyrus Khojasteh. Drug Metab Dispos February 2013 41:508-517.

QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

BENEFIT FROM THE RESOURCES OF A GLOBAL CRO

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of bioanalytical services to support drug development needs from discovery, through clinical development and regulatory filing.



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